UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

RICKY BURNS,
Plaintiff,
v.
ASTRAZENECA LP, a Delaware Company, ASTRAZENECA PHARMACEUTICALS LP, a Delaware Company, ASTRAZENECA AB, a Foreign Corporation, ASTRAZENECA PLC, a Foreign Corporation, and ASTRAZENECA UK LIMITED, a Foreign Corporation
Defendants.

COMPLAINT

NOW COMES the Plaintiff, RICKY BURNS (herein referred to as "Plaintiff"), by and through his attorneys, THE LAW GROUP, LTD., and complaining of the Defendants, ASTRAZENECA LP, ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, ASTRAZENECA PLC, and ASTRAZENECA UK LIMITED herein referred to collectively as "Defendants"), and states as follows:

I. INTRODUCTION

1. This is a civil action brought on behalf of Plaintiff regarding personal injury damages which occurred as a result of Plaintiff's ingestion of the prescription drug, Seroquel, also known as Quetiapine Fumarate (hereinafter referred to as "Seroquel"). Seroquel was manufactured, marketed, distributed and sold to Plaintiff by Defendants and/or its representatives.

II. PARTIES

A. PLAINTIFF

2. Plaintiff Ricky Burns is a resident of Niles Illinois. Plaintiff was initially prescribed Seroquel in 2004 for Bipolar Disorder. On or about February 12, 2009, Plaintiff was originally diagnosed with Type II Diabetes Mellitus.

B. DEFENDANTS

3. Defendant ASTRAZENECA LP, is a company organized and existing under the laws of the State of Delaware with its principal place of business at 50 Otis Street, Westborough, MA 01581- 4500. At all material times herein, this Defendant has conducted business and advertised, marketed, promoted, sold and/or distributed Seroquel in the State of Illinois.

4. Defendant ASTRAZENECA PHARMACEUTICALS LP, is the general partner of AstraZeneca LP, and is a company organized and existing under the laws of the State of Delaware with its principal place of business in Delaware. At all material times herein, this Defendant has conducted business and advertised, marketed, promoted, sold and/or distributed Seroquel in the State of Illinois.

5. Defendant AstraZencca UK Limited is a company incorporated under the laws of England and Wales and has a registered office in London, England. Defendant AstraZeneca UK Limited is the holder of the new Drug Application by which the U.S. Food and Drug Administration first granted approval for Seroquel.

6. Defendant ASTRAZENECA AB, is the general partner of AstraZeneca Pharmaceuticals LP, and is a foreign company with its principal place of business at SE-151 85, SOdertiilje, Sweden. At all material times herein, this Defendant

has conducted business and advertised, marketed, promoted, sold and/or distributed Seroquel in the State of Illinois.

7. Defendant ASTRAZENECA PLC, is the ultimate parent company of all Defendants, and is a foreign company with its principal place of business at IS Stanhope Gate, London, WIK ILN, England, United Kingdom. This Defendant's principal place of business in the United States is located at 35 Gatehouse Drive, Waltbam, MA 02451. At all material times herein, this Defendant has conducted business and advertised, marketed, promoted, sold and/or distributed Seroquel in the State of Illinois.

III. JURISDICTION & VENUE

8. The Court has jurisdiction over this lawsuit under 28 U.S.C. §1332(a)(I) because Plaintiff is a citizens of different state from all Defendants and the amount in controversy exceeds $75,000, excluding interest and costs. This Federal Court sitting in diversity may exercise personal jurisdiction over Defendants under the Illinois long-arm statute, which permits jurisdiction over a person to the full extent of the due process clause of the United States Constitution. Venue is proper in this Court under 28 U.S.C. §1391(a)(I) because all Defendants "reside" in this judicial district as that term is defined in 28 U.S.C. §1391(c) and other law, under 28 U.S.C. §1391(a)(2) in that a substantial part of the events or omissions giving rise to these claims arose in this judicial district, and/or, under 28 U.S.C. §1391(a)(3) because there is no district in which the action may otherwise be

brought and at least one Defendant is subject to personal jurisdiction in this district.

IV. FACTS

9. At all times relevant herein, Defendants were in the business of designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing pharmaceuticals, including Seroquel, for use by the mainstream public, including Plaintiff.

10. Seroquel is among a group of drugs known as "atypical antipsychotics" or "second generation antipsychotics," and was initially approved in September 1997 by the U.S. Food and Drug Administration (hereinafter the "FDA").

11. Like schizophrenia, bipolar I disorder is relatively rare, also affecting less than one percent of the population of the United States.

12. Despite its limited approval, and relatively small indicated target population, in 2005, Seroquel had become the thirteenth best-selling drug in the United States, and has passed Zyprexa and Risperdal as the highest selling antipsychotic in the United States. Seroquel's worldwide sales in 1998, its first full year on the market were a modest $63 million. According to Defendants' 2005 Annual Report, worldwide Seroquel sales exceeded $2.76 billion, which made Seroquel Defendants' second highest selling drug behind only Nexium at $4.63 billion.

13. Critical to this blockbuster success was Defendants' aggressive marketing of Seroquel, which consisted chiefly of overstating the drug's uses (including massive off-label promotion), while understating and consciously concealing its life-threatening side effects.

14. Medical literature dating back as far as the 1950s, demonstrated that Seroquel, like other antipsychotics had the potential to cause diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects. Defendants' own pre-clinical studies regarding Seroquel confirmed this to Defendants. Despite this knowledge, Defendants never attempted to provide an adequate warning label until they were finally forced to do so by the FDA.

15. Shortly after Seroquel's product launch and first widespread usage, the number of adverse event reports involving diabetes-related illnesses associated with Seroquel, spiked. These reports were filed with the FDA's Medwatch database, all of which were reported and known to Defendants.

16. On September II, 2003, the FDA informed all manufacturers of atypical antipsychotic drugs, including Defendants, that due to an increasing prevalence of diabetes-related illnesses associated with this class of drugs, all labeling must bear the following language in the Warnings section:

> "Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemiarelated adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics.

> Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug."

17. Despite the FDA action, Defendants waited until January 30, 2004 to send out a "Dear Doctor" letter attempting to advise treating physicians of the new warnings. On April 22, 2004 Defendants were forced to send out a revised "Dear Doctor" letter due to the fact that the first one was misleading, as it potentially downplayed the need to continually monitor a patient's blood sugar levels while on the drug. This critical information did not make it into the *Physicians' Desk Reference* until the 2005 edition.

18. In January 2006, Defendants were notified that the U.S. Attorney's Office in Los Angeles, California had commenced an investigation of Defendants' field promotional activities related to its products, including Seroquel.

19. Despite Defendants' knowledge regarding the safety risks its drug posed, they continued to ignore, downplay, sidestep, and delay the dissemination of open and frank information that patients and physicians needed to avoid the life-threatening injuries that Seroquel could cause. As a result of this callous disregard for human safety in the name of profits, Plaintiff has suffered and continues to suffer the injuries damages and losses complained herein.

20. Pharmaceutical manufacturers have a duty to design and formulate drugs that are safe and effective for their intended uses.

21. The safety of consumers should always be a primary concern for pharmaceutical manufacturers.

22. The benefits of a drug should always outweigh the potential risks associated with the drug.

23. Pharmaceutical manufacturers have a duty to ensure that the public is aware of the risks associated with their products.

24. Pharmaceutical manufactures should notify physicians and patients when they become aware of additional safety risks with products currently on the market.

25. Pharmaceutical manufacturers should not actively conceal a products additional safety risks from physicians and/or their patients.

26. Pharmaceutical manufacturers must ensure that information contained on product labels is truthful and not misleading.

27. Physicians rely, in part, on label information to determine if a drug is safe and efficacious for a particular patient.

28. A drug shall be deemed misbranded if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

29. The severity of adverse events associated with a specific drug should be equally important as the frequency of occurrence.

30. A drug becomes unreasonably dangerous when its risks are greater than those that would be contemplated by an ordinary user.

31. A drug should be safe and fit for its intended purpose, namely that it can be prescribed and taken without an unnecessary risk of injury.

VI. CAUSES OF ACTION

A. STRICT PRODUCTS LIABILITY

32. Defendants are liable as the manufacturers, distributors and/or sellers of Seroquel because Seroquel, when sold, was in a defective and unreasonably dangerous condition. Defendants owed a strict duty to Plaintiff not to harm Plaintiff through the use of their drug.

1. DESIGN DEFECT

33. Seroquel was defective in design and/or formulation in that, when it left the hands of Defendants and/or its representatives, the foreseeable risks of serious harm posed by the drug outweighed its alleged benefits. The foreseeable risks of serious harm were so great that Plaintiff, and the general public, having known of such foreseeable risks and alleged benefits, would not have ingested Seroquel.

34. Seroquel was placed into the stream of commerce by Defendants, acting through authorized agents, servants, employees and/or representatives. Plaintiff

was prescribed Seroquel by Plaintiff's physicians and used the drugs in a manner reasonably foreseeable by Defendants.

35. The Seroquel ingested by Plaintiff was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. As a result of his use of Seroquel, Plaintiff suffered severe, permanent and disabling injuries and related damages.

2. MARKETING DEFECT-INADEQUATE AND IMPROPER WARNINGS

36. Seroquel was marketed to physicians to be prescribed to their patients and was marketed and advertised directly to the consuming public. Seroquel, as manufactured and supplied to healthcare professionals and the general public, was unaccompanied by proper warnings regarding the serious risks of ingesting the drug. The information provided to consumers did not reflect Defendants' knowledge that Seroquel was not safe and effective as indicated in its aggressive marketing campaign, nor were consumers made aware that ingesting the drug could result in serious injury, pain and discomfort and/or death. Additionally, Defendants committed overt acts and issued doublespeak in order to downplay the truth which began to surface. This information began to emerge in the form of adverse event reports, medical studies, and the 2003 FDA labeling change mandate. Any attempts by Defendants to satisfy its duty to warn were compromised by the backdrop of Defendants' actions. Full and proper warnings that accurately and fully reflected the risks of serious injury and/or sudden death due to the ingestion of Seroquel should have been disclosed by Defendants.

37. Plaintiff was prescribed Seroquel by physicians who utilized the drug in a manner reasonably foreseeable by Defendants. Seroquel was expected to and did reach Plaintiff without substantial change in its condition as tested, manufactured, designed, labeled, packaged, marketed and distributed. Plaintiff was not aware of, and could not have reasonably discovered, the unreasonably dangerous nature of Seroquel.

38. As the producing cause and legal and direct result of the failure to warn consumers of the defective condition of Seroquel, as manufactured and/or supplied by Defendants and its representatives, Plaintiff has suffered severe, permanent and disabling injuries and related damages.

B. NEGLIGENCE

39. Defendants owed Plaintiff legal duties in connection with putting Seroquel into the marketplace to be ingested by potential patients such as Plaintiff. Defendants breached their duties, proximately causing Plaintiff's injuries. Specifically, Defendants failed to meet their duty to use reasonable care in the testing, creating, designing, manufacturing, labeling, packaging, marketing, selling, and warning of Seroquel. Defendants are liable for acts and/or omissions amounting to negligence, gross negligence and/or malice including, but not limited to the following:

a. Failure to adequately warn Plaintiff and Plaintiff's physicians of the respective known or reasonably foreseeable danger that Plaintiff would suffer a serious injury or death by ingesting Seroquel;

b. Failure to adequately warn Plaintiff and Plaintiff's physicians of the known or reasonably foreseeable danger that Plaintiff would

suffer a serious injury or death by ingesting Seroquel in unsafe doses;

c. Failure to use reasonable care in testing and inspecting Seroquel, so as to ascertain whether or not it was safe for the purpose for which it was designed, manufactured and sold;

d. Failure to use reasonable care in implementing and/or utilizing a reasonably safe design in the manufacture of Seroquel;

e. Failure to use reasonable care in the process of manufacturing Seroquel in a reasonably safe condition for the use for which it was intended;

f. Failure to use reasonable care in the manner and method of warning Plaintiff and Plaintiff's physicians as to the danger and risks of using Seroquel in unsafe doses;

g. Failing to use reasonable care in maintaining its continuing duty to warn Plaintiff and Plaintiff'' physicians of after acquired knowledge;

h. Failure to use reasonable care under the circumstances in acquiring information about patient experience with actual usage of Seroquel, observed effects of Seroquel, monitoring and analyzing information on the quality, safety, efficacy, and all other aspects of reasonable vigilance and ongoing monitoring of a dangerous pharmaceutical (e.g. negligent pharmacovigilance); and,

i. Such further acts and/or omissions that may be proven at trial.

40. The above-described acts and/or omissions of Defendants were direct and proximate causes of Plaintiff's injuries, diseases, and damages complained of herein.

C. INTENTIONAL MISREPRESENTATION

41. Defendants made material representations that were false and that were either known to be false when made or were asserted recklessly without knowledge of their truth. These misrepresentations involved material facts concerning the

character and quality of the drug in question, and reasonably implied to consumers that Seroquel was safe and would not cause injury. Defendants failed to disclose material facts regarding the dangerous propensities of Seroquel that were known to Defendants and within the knowledge of Defendants. Defendants were well aware of the lack of knowledge on behalf of consumers such as Plaintiff, and of the incredible disparity between Defendants' and Plaintiff's opportunity to fully appreciate and discover the dangerous character of Seroquel. By failing to disclose the knowledge known and appreciated by Defendants, Defendants intended to induce Plaintiff and his physicians into continuing to prescribe, purchase and use Seroquel without worry. Without appropriate knowledge and the benefit and right of informed choice regarding the dangers known to Defendants, Plaintiff's suffered the injuries, diseases, and damages complained of herein.

42. Defendants had in its possession adverse drug event reports, drug studies, and other documentation about Seroquel, and yet made the following misrepresentations:

a. Misrepresentations regarding the respective frequency of Seroquel-related adverse event reports or occurrences in the drug's label, package insert or PDR label;

b. Misrepresentations as to the respective existence, occurrence and frequency of occurrences, severity and extent of the overall risks of Seroquel;

c. Misrepresentations as to the respective efficacy of Seroquel for both FDA approved and non-approved indications;

d. Misrepresentations as to the respective number of adverse events and deaths reported with the use of Seroquel; and,

e. Misrepresentations regarding the respective nature, seriousness, and severity of adverse events reported with the use of Seroquel.

43. Defendants intended that these misrepresentations be relied upon by physicians, including Plaintiff's physicians, healthcare providers and consumers. Plaintiff did rely upon the misrepresentations that caused Plaintiff's injuries.

44. As a proximate cause and legal and direct result of Defendants' misrepresentations, Plaintiff's suffered the injuries, diseases, and damages complained of herein.

D. NEGLIGENT MISREPRESENTATION

45. Long after Defendants became aware of the risks posed by the ingestion of Seroquel, Defendants failed to communicate those risks to Plaintiffs and the general public. Instead, Defendants continued to represent in its marketing that Seroquel was safe and effective.

46. Plaintiffs bring this cause of action against Defendants under the theory of negligent misrepresentation for the following reasons:

a. Defendants, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Seroquel, in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

b. These misrepresentations were made in the course of Defendants' sales of Seroquel to the general public, Plaintiff and Plaintiff's physicians for the purpose of inducing continued sales and use of Seroquel;

c. Defendants knew that the risk of severe physical harm existed as a result of its misrepresentations;

d. Plaintiff and Plaintiff's healthcare providers justifiably relied on Defendants' misrepresentations; and,

e. Consequently, Plaintiffs ingested Seroquel to Plaintiff's detriment.

47. Defendants' negligent misrepresentations were direct and proximate causes of Plaintiff's injuries, diseases, and damages complained of herein.

E. EXPRESS WARRANTY

48. Defendants are merchants and/or sellers of Seroquel. Defendants sold Seroquel to consumers, including Plaintiff, for the ordinary purpose for which such drugs are used by consumers. Defendants made representations to Plaintiff about the quality or characteristics of Seroquel by affirmation of fact, promise and/or description.

49. The representations by Defendants became part of the basis of the bargain between Defendants and Plaintiffs. Seroquel did not comport with the representations made by Defendants in that it was not safe for the use for which it was marketed. This breach of warranty by Defendants was a proximate cause of the injuries and monetary loss suffered by Plaintiff.

F. IMPLIED WARRANTY

1. WARRANTY OF MERCHANTABILITY

50. Defendants are merchants and/or sellers of Seroquel. Plaintiff purchased Seroquel as placed in the stream of commerce by Defendants and used it for the ordinary purpose for which such drugs are used by consumers. At the time it was purchased by Plaintiff, Seroquel was not fit for the ordinary purpose for which such drugs are used because it was not manufactured, designed or marketed in a

manner to accomplish its purpose safely. Defendants' breach of its implied warranty of merchantability was a direct and proximate cause of Plaintiffs' injuries, diseases, and damages complained of herein.

2. WARRANTY OF FITNESS

51. Defendants placed Seroquel into the stream of commerce with the knowledge that Plaintiffs were purchasing said drugs for a particular purpose. Further, Defendants knew, or should have known, that Plaintiff was relying on Defendants' skill or judgment to select goods fit for Plaintiff's purpose.

52. Defendants delivered goods that were unreasonably dangerous and unfit for Plaintiff's particular purpose, in that they were defectively designed and did not come with adequate warnings.

53. Defendants' failure to select and sell a product which was reasonably safe for its intended use was a direct and proximate cause of Plaintiff's injuries, diseases, and damages complained of herein.

G. CIVIL CONSPIRACY

54. Defendants knowingly agreed, contrived, combined, confederated and conspired amongst themselves and with captured research groups, physicians, and trade groups to cause Plaintiff's injuries, diseases, and damages by continuous downplaying of the risks associated with Seroquel in the name of more sales. They further conspired to deprive consumers such as Plaintiff of the opportunity of informed free choice as to whether to use Seroquel or to expose themselves to its hidden dangers. Defendants committed the above described wrongs by willfully

misrepresenting and suppressing the truth as to the risks and dangers associated with the use of Seroquel.

55. In furtherance of said conspiracies, Defendants and its co-conspirators performed the following overt acts:

a. For years, Defendants and its co-conspirators, have been in possession of medical and scientific data, literature, test reports, doctors' inquiries and adverse event reports which clearly indicated that Seroquel and other antipsychotic drugs could cause diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects; and,

b. Despite the medical and scientific data, literature, and test reports possessed by and available to Defendants, Defendants and its co-conspirators fraudulently, willfully, and maliciously:

i. Withheld, concealed, and suppressed said medical and scientific data, literature, test reports, doctors' inquiries and adverse event reports regarding the risks of diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects from the general public, Plaintiff and Plaintiff's physicians; and

ii. Caused to be released, published and disseminated medical and scientific data, literature, test reports, and marketing and promotional materials containing information and statements regarding the risks of diabetes, diabetes-related injuries (e.g. severe weight gain, hyperglycemia, diabetic ketoacidosis), pancreatitis, cardiovascular complications, and other severe adverse effects, which Defendants knew were incorrect, incomplete, outdated and misleading.

56. By the false and fraudulent representations, omissions and concealments set forth above, Defendants and its co-conspirators intended to induce Plaintiff and Plaintiff's physicians to rely upon said false and fraudulent representations, omissions and concealments, to continue to expose themselves to the dangers inherent in the use of Seroquel.

57. As a result of their participation in the joint venture of designing, testing, monitoring, manufacturing, labeling, advertising, marketing, promoting, selling and distributing Seroquel, all Defendants can be held liable jointly and severally for Plaintiffs' injuries, diseases, and damages complained of herein.

58. Defendants' participation in this conspiracy was a direct and proximate cause of Plaintiff's injuries, diseases, and damages complained of herein.

VII. DAMAGES

59. Upon trial of this case, Plaintiff respectfully request the Court and Jury to determine the amount of loss Plaintiff has incurred in the past and will incur in the future, not only from a financial standpoint, but also in terms of good health and freedom from pain and worry. There are certain elements of damages provided by law that Plaintiff is entitled to have the Jury separately consider to reasonably compensate Plaintiff for the injuries, damages and losses incurred, as well as those to be incurred in the future. Plaintiff has been damaged as a result of Defendants' acts and omissions complained of herein in the following particulars:

a. Plaintiff has incurred medical, pharmaceutical, hospital, and related expenses and may be reasonably expected to incur additional expenses in the future due to the progressive nature of his injuries;

b. The likely progression and related life-threatening medical conditions reasonably anticipated to accompany Plaintiff's injuries will require lifetime medical monitoring as well as domestic help and nursing care as his conditions deteriorates;

c. Plaintiff is subject to an extraordinarily increased likelihood of developing heart disease, strokes, high blood pressure, blindness, kidney disease, nervous system disease, amputations, dental disease, sexual dysfunction, and other diabetes related complications;

d. Plaintiff has been and will otherwise be prevented from participating in and enjoying the benefits of a full and complete life;

e. Plaintiff asserts a claim for prejudgment interest on all elements of damages as allowed by law.

VIII. PUNITIVE DAMAGES

60. At all times relevant hereto, Defendants had actual knowledge of the defective nature of Seroquel as set forth herein and continued to design, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the public's health and safety and in conscious disregard of the foreseeable serious harm caused by the drug. Defendants' conduct exhibits such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence, malice and/or willful and intentional disregard for the safety and rights of consumers of its drugs such as Plaintiff. Plaintiff is therefore entitled to punitive damages.

IX. JURY DEMAND

61. Plaintiff hereby requests a trial by jury on all issues in this case.

X. PRAYER

62. WHEREFORE, PREMISES CONSIDERED, Plaintiff RICKY BURNS prays that upon final hearing, Plaintiff has and recover judgment from Defendants, pursuant to the above and foregoing allegations in such amounts as found proper by a jury, which is in excess of the jurisdictional minimum of this court and as the evidence may show proper at the time of trial, together with interest thereon at the legal rate; punitive and/or exemplary damages; Plaintiff's costs and attorneys' fees expended in prosecuting this matter; and for such other and further relief,

both general and special, at law and in equity, to which Plaintiff may be justly entitled.

Respectfully Submitted,

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